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IN THE

Supreme Court of the United States

NATIONAL UROLOGICAL GROUP, INC., ET AL.,
Petitioners,

v.

FEDERAL TRADE COMMISSION,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1) Whether the decision below violated Petitioners' right to commercial free speech by applying standards and imposing restrictions on ingredient specific advertising that are more restrictive than necessary.

2) Whether the decision below effectively imposed a new standard for dietary supplement products, in contrast to the requirements of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), by requiring a dietary supplement producer to have clinical studies of its products prior to advertising such products.

3) Whether the decision below established a new standard for factual questions in cases alleging false advertising when it resolved, as a matter of law, that Petitioners' advertising was false and unsubstantiated, rather than allowing Petitioners to present their evidence to a trier of fact.

PARTIES TO THE PROCEEDING

Pursuant to Rule 14.1(b), the following list identifies all of the parties appearing here and before the United States Court of Appeals for the Eleventh Circuit.

The petitioners here and appellants below are National Urological Group, Inc., Hi-Tech Pharmaceuticals, Inc., Jared Robert Wheat, Thomasz Holda, Stephen Smith, and Terrill Mark Wright, M.D.

The respondent here and appellee below is the Federal Trade Commission.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, Petitioners state that there are no parent corporations or publicly held corporations that own 10% or more of the stock of National Urological Group, Inc. or Hi-Tech Pharmaceuticals, Inc.

TABLE OF CONTENTS

Page

QUESTIONS PRESENTED i

PARTIES TO THE PROCEEDING ii

CORPORATE DISCLOSURE STATEMENT ii

TABLE OF CONTENTS iii

TABLE OF AUTHORITIES vi

OPINIONS BELOW 1

JURISDICTION 1

CONSTITUTIONAL AND STATUTORY PROVISIONS 1

STATEMENT OF THE CASE 2

I. The FTC Act 2

II. DSHEA 3

III. Procedural and Factual History 5

REASONS FOR GRANTING THE PETITION 8

I. The Eleventh Circuit's Decision Conflicts with Decisions of the D.C. Circuit in Two Important Areas of First Amendment Jurisprudence 8

Table of Contents continued

Page

A. Commercial Speech 9

B. Vagueness 14

II. The Eleventh Circuit's Decision Conflicts with an Existing Statutory Scheme 16

III. The Eleventh Circuit's Decision Conflicts with the Decisions of Other Courts of Appeals in False Advertising Cases 21

CONCLUSION 25

FTC v. Nat'l Urological Group, Inc., 356 Fed. App'x 358 (11th Cir. 2009) 1a

FTC v. Nat'l Urological Group, Inc., F. Supp. 2d 1167 (N.D. Ga. 2009) 3a

FTC v. Nat'l Urological Group, Inc., denial of Pet'n for Rehearing 88a

CONSTITUTIONAL AND STATUTORY PROVISIONS 90a

I. U.S. Const., Amend. 1 . . . . . 90a

Table of Contents continued

Page

II. The FTC Act 90a

III. DSHEA 91a

TABLE OF AUTHORITIES

Page(s)

CONSTITUTIONAL PROVISIONS

U.S. Const., Amend. 1 . . . . . *passim*

CASES

Alexander v. Cahill, 598 F.3d 79 (2d Cir. 2010) . . 10

Alliance for Natural Health US v. Sebelius, – F. Supp. 2d –, 2010 WL 2110071 (D.D.C. May 27, 2010) 13

Anderson v. Liberty Lobby, Inc., 477 U.S. 242 (1986) 23

Borgner v. Brooks, 284 F.3d 1204 (11th Cir. 2002) 10

Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557 (1980) 8-10, 12

FTC v. Brown & Williamson Tobacco Corp., 778 F.2d 35 (D.C. Cir. 1985) 21, 22

FTC v. Lane Labs-USA, Inc., 2009 WL 2496532 (D.N.J. Aug. 11, 2009) 18

FTC v. Pantron I Corp., 33 F.3d 1088 (9th Cir. 1994) 21

Table of Authorities continued

Page(s)

FTC v. QT, Inc., 448 F. Supp. 2d 908 (N.D. Ill. 2006) 22

In re R.M.J., 455 U.S. 191 (1982) 10

In re Schering Corp., 118 F.T.C. 1030 (1994) 3

Nat'l Bakers Servs., Inc. v. FTC, 329 F.2d 365 (7th Cir. 1964) 21, 22

Nat'l Urological Group, et al., v. FTC, 64 F. Supp. 2d 1167 (N.D. Ga.), *aff'd*, 356 Fed. App'x 358 (11th Cir. 2009) 1

Nutritional Health Alliance v. Shalala, 144 F.3d 220 (2d Cir. 1998) 3, 24

Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999) 8, 11-15

Pearson v. Shalala, 14 F. Supp. 2d 10 (D.D.C. 1998) 11

STATUTES

15 U.S.C. § 45(a) 1, 2, 6

15 U.S.C § 52 . . . . . 1, 2, 6

15 U.S.C. § 53(b) 1, 5

Table of Authorities continued

Page(s)

15 U.S.C. § 57a 20

21 U.S.C. § 321 . . . . . 1, 3, 4

21 U.S.C. § 331(v) 4

21 U.S.C. § 342(f) 4, 16

21 U.S.C. § 343(r)(6) 5, 16, 18

21 U.S.C. § 350b(c) 4

28 U.S.C. § 1254(1) 1

MISCELLANEOUS

21 C.F.R. § 101.14 . . . . . 11, 18

Pub. L. No. 103-417, 108 Stat. 4325 (1994) 3

CANTOX Health Services International, *Safety Assessment and Determination of a Tolerable Upper Limit for Ephedra,* (Dec. 19, 2000) 19

FTC publication, Dietary Supplements: An Advertising Guide for Industry (2001) 2, 15

Table of Authorities continued

Page(s)

Morton and Maglione, *Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects,* Evidence Report/Technology Assessment No. 76 (Feb. 2003) 19

Petitioners respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eleventh Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App. 1a)[1] is reported at 356 Fed. App'x 358 (11th Cir. 2009). The opinion of the district court (App. 3a-87a) is reported at 645 F. Supp. 2d 1167 (N.D. Ga. 2009).

JURISDICTION

The court of appeals denied the petition for rehearing and rehearing *en banc* on April 26, 2010.

This petition is timely filed within 90 days of that decision. Petitioner invokes jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS

This case involves the First Amendment to the United States Constitution and provisions of the Federal Trade Commission Act, 15 U.S.C. §§ 45(a), 52 and 53(b). In addition, this case implicates the provisions of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. 321, *et seq.* The relevant statutory provisions are reprinted at App. 90a-93a.

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[1] References to App. are to the appendix to the petition.

STATEMENT OF THE CASE

I. The FTC Act.

The Federal Trade Commission ("FTC") is an independent agency of the United States Government created by statute. The FTC enforces the Federal Trade Commission Act (the "Act"), which prohibits unfair or deceptive acts or practices in or affecting commerce. 15 U.S.C. § 45(a). In addition, the Act prohibits false advertising for food, drugs, devices, services, or cosmetics in or affecting commerce. 15 U.S.C. § 52. With respect to such advertising, FTC regulations require that advertisements be (1) truthful and not misleading and (2) supported by adequate substantiation for product claims prior to dissemination.

According to the FTC, to be adequately substantiated, advertisements related to a health benefit must be based upon "competent and reliable scientific evidence." *See FTC publication, Dietary Supplements: An Advertising Guide for Industry* (2001) at 9. The FTC has defined "competent and reliable scientific evidence" as "tests, analyses, research, studies, or other evidence based upon the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results" that support the specific claims made in the advertising. *Id.; see, e.g., In re Schering Corp.*, 118 F.T.C. 1030, 1127 (1994) (consent order).

II. DSHEA.

The Federal Food, Drug and Cosmetic Act (the "FFDCA") grants the Food and Drug Administration ("FDA") the authority to regulate, among other items, "drugs." Under the FFDCA, "drugs" are defined as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(B)(C).

In 1994, Congress amended the FFDCA by enacting the Dietary Supplement Health and Education Act ("DSHEA"),[2] which established a new regulatory category for dietary supplements. Congress enacted DSHEA to provide consumers greater access to and more information about dietary supplement products and to reduce governmental regulation. *See Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 224 (2d Cir. 1998) (with DSHEA, Congress moved to "narrow the reach of the FDA's preauthorization scheme 'out of concern over excessive regulation of dietary supplements and the suppression of truthful information'").

In contrast to "drugs," under DSHEA "dietary supplements" are defined as:

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[2] Pub. L. No. 103-417, 108 Stat. 4325 (1994).

> [A] product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D) or (E).

21 U.S.C. § 321(ff)(1). Under DSHEA, dietary supplements are regulated as a subset of foods, rather than drugs. *Id.*[3] Unlike drugs, dietary supplements are *legally presumed* to be safe under DSHEA. *See* 21 U.S.C. § 342(f)(1)(A) (dietary supplements cannot be removed from the marketplace without the FDA first proving adulteration). As a result, dietary supplement manufacturers are not required to submit their products to pre-market clinical testing and scientific review for safety or efficacy. *See* 21 U.S.C. §§ 331(v) and 350b(c) (recognizing as lawfully marketable every dietary ingredient marketed in the United States prior to the effective date of DSHEA, October 14, 1994).

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[3] Section 321(ff) provides that "[e]xcept for purposes of 201(g) [the definition of a drug], a dietary supplement shall be deemed to be a food within the meaning of this Act."

In addition, dietary supplement manufacturers are permitted to place certain types of claims on their products without prior FDA approval. 21 U.S.C. § 343(r)(6). Specifically, DSHEA allows the manufacturer to include the following claims: (1) statements asserting "a benefit related to a classical nutrient deficiency disease and disclos[ing] the prevalence of such disease in the United States"; (2) statements commonly known as "structure-function claims" that "describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans [and] to characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function"; and (3) declarations of "general well-being from consumption of a nutrient or dietary ingredient." 21 U.S.C. § 343(r)(6)(A). These type of claims are permissible under DSHEA if the manufacturer has "substantiation" that the "statement is truthful and not misleading" and the label contains the following disclaimer in boldface type: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." 21 U.S.C. § 343(r)(6)(B), (C).

III. Procedural and Factual History.

In this case, the FTC brought litigation pursuant to § 13(b) of the FTC Act, 15 U.S.C. § 53(b), to secure injunctive and other equitable relief against National Urological Group, Inc., Hi-Tech Pharmaceuticals, Inc., Jared Robert Wheat, Thomasz Holda, Stephen Smith, and Terrill Mark

Wright, M.D. ("Petitioners"). According to the FTC, between 2001 and 2003, Petitioners made false and deceptive representations in the marketing and advertisement of two weight loss dietary supplement products – Thermalean® and Lipodrene® – and a sexual enhancement product – Spontane-ES®.

The FTC asserted that Petitioners' advertisements were false and not supported by adequate substantiation, in violation of § 5 of the Act, 15 U.S.C. § 45(a), and § 12 of the Act, 15 U.S.C. § 52. In making its allegations, the FTC acknowledged that it did not contend that any individual statement in the advertisement was not 100% accurate. Instead, the FTC contended that its claims were derived from the overall net impressions created by the advertising. Thus, the FTC argued that the advertising implied that the safety and efficacy claims were for the product as a whole rather than the ingredients or components as stated in the advertising, despite that the advertising actually focused on the ingredients and components of the dietary supplement products, rather than the products themselves.

Petitioners had purposefully used scientific studies of the active ingredients and components of the products to develop the products at issue and then designed the advertisements to conform to the results of the studies. The referenced studies consisted of independent, double-blind, placebo-controlled clinical trials and scientific studies found in well-respected medical journals. Petitioners relied upon these studies and comments for scientific

support that the ingredients in the products were safe and effective as represented. Among the studies were numerous clinical studies and comments expressed by independent "think-tank" organizations and others, as well as meta-studies such as the CANTOX Report and the RAND Report. *See* note 7, *infra.* These reports concluded that the major ingredients of the products at issue – ephedra/ephedrine and caffeine – were safe and effective in promoting weight loss as represented.

Upon cross-motions for summary judgment, the district court denied Petitioners' motions and granted summary judgment in favor of the FTC. (App. 86a.) In so doing, the court rejected Petitioners' arguments that the advertising had protection under the First Amendment (App. 20a-22a) and that the FTC's "competent and reliable scientific evidence" standard was void for vagueness (App. 22a-25a).

On appeal, Petitioners challenged the district court's rejection of their two First Amendment arguments. Moreover, Petitioners argued that the district court resolved as a matter of law issues that are properly reserved for a trier of fact. In their petition for rehearing, Petitioners also argued that the court's opinion eviscerated the statutory scheme Congress promulgated with DSHEA. Despite the district court's constitutional errors and the circuit splits the case created, the Eleventh Circuit Court of

Appeals summarily disposed of all of Petitioners' arguments in a three-sentence *per curiam* opinion.[4]

REASONS FOR GRANTING THE PETITION

I. The Eleventh Circuit's Decision Conflicts with Decisions of the D.C. Circuit in Two Important Areas of First Amendment Jurisprudence.

The court of appeals' decision has effectively and unnecessarily chilled the First Amendment rights of dietary supplement manufacturers, including Petitioners, to advertise their products. Furthermore, the court's ruling is now in conflict with the D.C. Circuit in regard to the constitutional right to commercial speech for such dietary supplement manufacturers. *See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

The advertising in question involved commercial speech protected by the First Amendment. *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980). As explained above, in an effort to comply with the FTC's standards, Petitioners based their advertising claims upon ingredient-specific substantiation, namely, independent, double-blind, placebo-controlled clinical trials of the components and ingredients of the referenced products. The FTC conceded in discovery that "it did not contend that any individual statement in the advertisement was

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[4] Because the court of appeals merely stated that it agreed with the district court's "well-reasoned" opinion, this petition treats the district court's opinion as that of the court of appeals.

not 100% accurate." Nevertheless, the court failed to analyze Petitioners' advertising under the standards of *Central Hudson*. Moreover, the court failed to require the FTC to provide any clarity to its vague standard of "competent and reliable scientific evidence."

A. Commercial Speech.

Under *Central Hudson*, to determine the constitutionality of commercial speech, the courts apply a four-step process:

> At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than necessary to serve that interest.

Central Hudson, 447 U.S. at 566.

The first prong of the *Central Hudson* test (speech must not be false) applies only to *inherently false* advertising. As this Court has explained:

> Truthful advertising related to lawful activities is entitled to the protections of the First Amendment. But when the particular content or method of the advertising suggests that it is inherently misleading or when experience has proved that in fact such advertising is subject to abuse, the States may impose appropriate restrictions. Inherently misleading advertising may be prohibited entirely. But the States may not place an absolute prohibition on . . . potentially misleading information . . . if the information also may be presented in a way that is not deceptive.

In re R.M.J., 455 U.S. 191, 203 (1982); *see, e.g., Alexander v. Cahill*, 598 F.3d 79, 89 (2d Cir. 2010); *Borgner v. Brooks*, 284 F.3d 1204, 1210-11 (11th Cir. 2002).

In the proceedings below, the FTC claimed, and the court agreed, that Petitioners' advertising was inherently false. (App. 58a-59a.) As explained by the court, the advertising claims at issue necessarily were "inherently false" because clinical testing had not been conducted upon the products themselves. (App. 58a & n.21.) But other courts

have rejected this sort of "blanket falsity" in the context of regulations by the FDA. *See Pearson*, 164 F.3d at 655.

In *Pearson*, a group of dietary supplement manufacturers filed suit against the FDA in connection with the FDA's rejection of certain health claims made by the manufacturers. *Pearson v. Shalala*, 14 F. Supp. 2d 10, 14 (D.D.C. 1998). The FDA, applying the "significant scientific agreement" standard set forth in 21 C.F.R. § 101.14, determined that the supporting evidence for the claims as offered by the manufacturers was insufficient to meet the standard but never explained how it measured evidence under the standard. *Pearson*, 164 F.3d at 653. Thus, the FDA declined to authorize the manufacturers' claims, finding the claims to be "*inherently* misleading and thus entirely outside the protection of the *First Amendment* as commercial speech." *Pearson*, 164 F.3d at 655 (emphasis in original). In addition, the FDA declined to consider an alternative to allow the manufacturers to make the claims with "corrective disclaimers" if the claims were only "potentially misleading." *Id.* at 654-55, 657. After the district court affirmed the FDA's decision, the court of appeals reversed. *Id.* at 651.

The D.C. Circuit first rejected the FDA's blanket denial of the health claims as "inherently misleading."

> As best we understand the government, its first argument runs

> along the following lines: that health claims lacking "significant scientific agreement" are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment *at the point of sale*. It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous . . . . We reject it.

Id. at 655 (internal citations omitted; emphasis in original).

The D.C. Circuit then addressed the FDA's argument that the health claims could be at least "potentially misleading." *Id.* Applying *Central Hudson*, the court held that there was not a "reasonable fit between the government's goals" of protecting public health and preventing consumer fraud and "the means chosen to advance those goals," namely, the rejection of plaintiffs' proposed health claims without consideration of disclaimers. *Pearson*, 164 F.3d at 656-58. In particular, the D.C. Circuit held that under the First Amendment commercial speech doctrine, there is a "preference for disclosure over outright suppression" and for "less restrictive and more precise means" of regulating commercial speech. *Id.* at 657-58. In the opinion of the court, the FDA's rejections of disclaimers without a showing that they were

insufficient to meet the government's goals demonstrated a disregard for "less restrictive" means of regulating the speech under the First Amendment. *Id.* at 659. As explained by the court, "[i]t is clear, then, that when government chooses a policy of suppression over disclosure – at least where there is no showing that disclosure would not suffice to cure misleadingness – government disregards a 'far less restrictive' means." *Id.* at 658.

The decision in this case directly conflicts with the D.C. Circuit's holdings regarding commercial speech and dietary supplements. The advertising at issue is not inherently false. The FTC conceded that the statements were literally true. *See Alliance for Natural Health US v. Sebelius,* – F. Supp. 2d –, 2010 WL 2110071, *11 (D.D.C. May 27, 2010) (finding the FDA's position that certain health claims were misleading was "particularly troubling" when the FDA had admitted that the claims were "literally true"). Even without the FTC's concession, the claims could not be considered "inherently false" when the resolution of whether the claims were false or unsubstantiated depended upon hundreds of pages of material, testimony, and experts who evaluated and opined as to the advertising claims and their substantiation.

Like the FDA, with its lack of analysis of the health claims in *Pearson* and *Alliance for Natural Health*, the FTC here has merely made an unsupported determination that Petitioners' advertising must necessarily be inherently false. In contrast to the court in *Pearson,* however, the courts

below accepted the FTC's unsupported determination. Manufacturers of dietary supplements are now subject to very differing standards, and their liability depends only upon the district in which suit is brought. Because the remedies a court may impose are potentially quite substantial (in this case, the court ordered consumer redress of almost $16 million), manufacturers will almost certainly adhere to the more speech-restrictive standard. This Court should address the conflict.

B. Vagueness.

The Eleventh Circuit's rejection of Petitioners' vagueness challenge to the FTC's "competent and reliable scientific evidence" standard also conflicts with the decision in *Pearson*. In *Pearson*, the plaintiffs argued that the FDA had an obligation to "articulate a standard a good deal more concrete than the undefined 'significant scientific agreement.'" *Pearson*, 164 F.3d at 654. In response, the FDA claimed that the "significant scientific agreement" standard was based upon "objective factors" and that its procedures for approving health claims under such standards satisfied constitutional muster. *Id.* at 653. The court of appeals disagreed, finding that the FDA was required to "giv[e] some definitional content to the phrase 'significant scientific agreement.'" *Id.* at 660.[5] As explained by

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[5] The court in *Pearson* analyzed the plaintiffs' claim pursuant to the APA's arbitrary and capricious standard. *Id.* at 660. As that court recognized, however, a First Amendment analysis would have reached the same conclusion. *Id.* at 660 & n.12.

the court, "[t]o refuse to define the criteria it is applying is equivalent to simply saying no without explanation." *Id.*

Here, the FTC's refusal (and the court's approval of such refusal) to define or provide explicit direction as to what qualifies as "competent and reliable scientific evidence" has created uncertainty and guesswork for the dietary supplement industry. At present, there are only a few relevant publications of the FTC that purport to offer "guidance" to the dietary supplement industry when developing advertising. Moreover, the referenced "guidance" does not provide sufficient certainty about the criteria the FTC uses to evaluate the scientific support of ingredient-specific claims. The FTC has not established any requirements for size, duration, or protocol for any scientific study, or any single fixed formula for the number or type of studies needed to substantiate a claim. The FTC only argues that its standard of "competent and reliable scientific evidence" is based upon "flexibility" in the type and amount of evidence required depending on the nature of the claim and how it is presented and qualified. *See FTC publication, Dietary Supplements: An Advertising Guide for the Industry.* This purported "guidance" provides little when faced with punitive enforcement proceedings such as the case at bar. Under these circumstances, the dietary supplement industry, including Petitioners, cannot be expected to review the FTC's vague standard and have any confidence as to whether the FTC would consider their substantiation for their advertising claims adequate

or not. The Court should resolve this conflict as well.

II. The Eleventh Circuit's Decision Conflicts with an Existing Statutory Scheme.

The opinion below not only creates a circuit split; it also eviscerates the existing statutory scheme that Congress created with the enactment of DSHEA. As noted earlier, DSHEA treats dietary supplements as a subset of food, not as drugs, and hence, it exempts them from the pre-market testing required of drugs. Instead, manufacturers of dietary supplements may rely on the testing of their active ingredients to manufacture and advertise their products. Under the new standard created by the opinions below, the FTC can trump the provisions of DSHEA as enforced by the FDA and mandate pre-market testing of the entire product, even though Congress specifically exempted dietary supplement manufacturers from that requirement.

Under DSHEA, dietary supplements are excluded from any requirement for pre-market clinical testing and scientific review. *See* 21 U.S.C. § 342(f)(1)(a). Furthermore, manufacturers of these supplements are permitted to make certain claims regarding the benefits of their products without prior FDA approval so long as the claim is based upon "substantiation" that is "truthful and not misleading." 21 U.S.C. § 343(r)(6). Given these statutory requirements, Petitioners developed and focused their products and the related advertising

upon the components and ingredients of the products, rather than the products as a whole.

As substantiation, Petitioners relied upon ample evidence of independent, double-blind, placebo-controlled clinical trials of the components and ingredients, a meta-analysis of those clinical trials, or both. Petitioners used this ingredient-specific substantiation as the basis for the advertising of their dietary supplement products by placing the same statistical figures and information found in the referenced studies explicitly in the advertisements. In other words, wherever Petitioners made a claim regarding any health benefits, Petitioners had a specific clinical study or scientific paper that supported the claim. For example, an advertisement for Thermalean stated that the "thermogenic components" of Thermalean resulted in 300% decrease in stored fat versus use of a placebo and 600% increase in total weight loss versus use of a placebo. These figures came from specific conclusions reached by respected scientists and clinical researchers in clinical studies involving ephedrine and caffeine.[6]

On its face, the evidence proffered by Petitioners meets the standards of the FDA under DSHEA with respect to health claims for dietary supplements. Under the FDA standard of

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[6] The studies relied upon by Petitioners were consistent with the FTC's expert's opinion that claims required substantiation in the form of appropriately analyzed, independent, well-designed, well-conducted, randomized, double-blind, placebo-controlled clinical trials.

"significant scientific agreement," a health claim is authorized for a dietary supplement when the FDA determines:

> based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is support by such evidence.

21 C.F.R. § 101.14(c).

As demonstrated by the amounts of scientific analysis and clinical trials, Petitioners had such substantiation to support the truthfulness of their claims on their products in accordance with DSHEA. *See* 21 U.S.C. § 343(r)(6). In addition, Petitioners had the referenced studies, as well as the advertising claims at issue, reviewed by and supported by a medical doctor and a pharmacologist prior to publication. *See, e.g., FTC v. Lane Labs-USA, Inc.*, 2009 WL 2496532, *8 (D.N.J. Aug. 11, 2009) (noting that prior to distribution of the advertisements in question, the defendant consulted experts who opined the scientific evidence supported the claims made in advertising). In short, it is readily apparent that Petitioners complied with the governmental

requirements for dietary supplements under DSHEA.[7]

Ingredient-specific substantiation such as this has been used by other dietary supplement manufacturers, as well as other industries that are not required to conduct pre-market testing and clinical studies. For example, toothpaste producers often refer to the active ingredient (sodium flourophosphate) in their product in providing substantiation for their advertising claims even though a clinical study of the product itself may not have been done. With respect to dietary supplements, advertising based upon ingredient-specific substantiation is particularly effective in light of the level of sophistication associated with the typical dietary supplement consumer.[8]

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[7] The meta-analysis used for substantiation included the following: (1) CANTOX Health Services International, *Safety Assessment and Determination of a Tolerable Upper Limit for Ephedra*, December 19, 2000 (the "CANTOX Report); and (2) Shekelle P., Morton, S., Maglione, m., et al., *Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects*, Evidence Report/Technology Assessment No. 76 (Prepared by Southern California Evidence-based Practice Center, RAND, under Contract No. 290-97-0001, Task Order No. 9), AHQR Publication No. 03-E022, Rockville, MD: Agency for Healthcare Research and Quality. February, 2003 (the "RAND Report"). Both of these analyses examined most of the same studies upon which Petitioners relied to support their advertising claims.

[8] The record below included the survey conducted by Dr. Glen Richey that revealed that the consumer intent to purchase the products at issue was driven by the claims in the advertisements regarding the components and ingredients, not the product. The survey indicated that purchasers of dietary

Contrary to the standards laid out by Congress and the FDA, the courts below held that that ingredient-specific scientific data could not substantiate the advertising claims. In other words, ingredient-specific substantiation for dietary supplements could not constitute "competent and reliable scientific evidence" under the FTC's standards. Under this ruling, to satisfy the FTC's standard of "competent and reliable scientific evidence," dietary supplement manufacturers are now subject to a *de facto* requirement to conduct pre-market clinical studies of the product itself. Such a precedent effectively eliminates DSHEA's exclusion of dietary supplements from the pre-market testing and clinical analysis typically reserved for drugs under the FFDCA. Moreover, it undermines the purpose of the enactment of DSHEA and the intent of Congress to provide greater access to dietary supplements and information with less regulation.[9] This Court's intervention is necessary to address the conflict between the statue and the holding below.

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supplements are more educated consumers than the ordinary consumer and can differentiate between whether a claim is about an ingredient or the product as a whole.

[9] It is important to recognize that, without the court's intervention, the FTC could not have issued a rule requiring pre-market clinical testing for dietary supplements without obtaining prior congressional approval and conducting rulemaking proceedings. *See* 15 U.S.C. § 57a.

III. The Eleventh Circuit's Decision Conflicts with the Decisions of Other Courts of Appeals in False Advertising Cases.

In affirming the district court's grant of summary judgment, the court of appeals created a circuit split on not one, but two, important issues in false advertising cases. First, the court determined that the advertisements were misleading as a matter of law. *Compare, e.g., FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 39-41 (D.C. Cir. 1985) (whether advertising is deceptive is a question of fact); *Nat'l Bakers Servs., Inc. v. FTC*, 329 F.2d 365, 367 (7th Cir. 1964) (same). Second, the court held that Petitioners' substantiation of its claims was inadequate as a matter of law. *Compare FTC v. Pantron I Corp.*, 33 F.3d 1088, 1096 (9th Cir. 1994) (whether a claim is substantiated is a question of fact).

The record in this case contained an abundance of evidence that created material factual disputes sufficient to withstand summary judgment. Petitioners submitted substantial amounts of evidence in the form of documents and testimony related to the meaning of the advertising claims at issue and the scientific support for such claims. In contrast, the FTC presented virtually nothing other than the testimony of its own experts who admittedly were never presented with copies of the actual advertisements at issue.

With respect to the advertising claims, Petitioners presented evidence that the components

and ingredients of the products at issue were the focus of Petitioners' advertising claims, rather than the products as a whole. Although "[t]he meaning of an advertisement, the claims or net impressions communicated to reasonable consumers, is fundamentally a question of fact," *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 957-58 (N.D. Ill. 2006), *citing Nat'l Bakers,* 329 F.2d at 367, the court below determined that the question of fact "may be resolved by the terms of the advertisement itself or by evidence of what consumers interpreted the advertisement to convey." (App. 29a.)

In considering charges of false and deceptive advertising, the consumer's "impression is the only true measure of deceptiveness" and thus, "if the lower court confronts an advertisement involving 'literally true or grammatically correct' statements, the trial judge cannot make a finding of deceptiveness unless the parties provide 'evidence of substance' about what 'the person to whom the advertisement is addressed find[s] to be the message.'" *Brown & Williamson Tobacco Corp.*, 778 F.2d at 39-41 (citations omitted). On this point, Petitioners submitted expert consumer survey evidence into the record that demonstrated that consumers interpreted the advertising at issue to focus on the components and ingredients, rather than the products. The FTC presented only the advertisements themselves. As Petitioners noted in their response to the FTC's motion for summary judgment, the FTC's reliance on the advertisements alone contradicted its own expert's opinion that only

the recipient of the advertising could ascertain the content and meaning thereof.

Instead of construing the evidence in the light most favorable to Petitioners, *see Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986), the court focused solely on whether the FTC's alleged claims were implied from the face of the advertisements. The court found that the advertisements made numerous *implicit* claims regarding the safety and efficacy of the products themselves and disregarded the literal language of the advertisements, which *explicitly* focused on the components and ingredients contained within the product. A rational trier of fact could have concluded that the express advertising claims were focused on the ingredients, rather than the products. The district court, however, dismissed this distinction as "meaningless." (App. 43a.)

The clinical studies and scientific support that Petitioners submitted as substantiation for the advertising claims similarly focused on the components and ingredients of the dietary supplement products. Petitioners presented the court with substantial evidence of independent, double-blind, placebo-controlled clinical trials of the components and ingredients, a meta-analysis of those clinical trials, or both. The clinical trials and other scientific evidence that Petitioners submitted created a question of fact as to whether Petitioners possessed "competent and reliable scientific evidence" to substantiate the advertising claims. From the evidence presented below, a reasonable trier of fact could have concluded that the

components and ingredients in the products at issue were safe and effective as advertised. The court nonetheless held as a matter of law that Petitioners' substantiation was inadequate.

Whether a manufacturer of dietary supplements has an opportunity to present its evidence to a trier of fact now depends on the circuit in which the FTC brings suit. This uncertainty, like the uncertainty regarding a manufacturer's commercial speech rights, neither promotes greater consumer information nor reduces government regulation. *See Nutritional Health Alliance*, 144 F.3d at 224. This Court should resolve that uncertainty.

CONCLUSION

Based upon the foregoing, Petitioners respectfully request that the Court grant their petition for writ of certiorari.

Respectfully submitted,

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